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17 February 2005

The Commissioner of Patents
Woden, A.C.T. 2606

Dear Commissioner,

Re:	International Patent Application No. PCT/2004/000578
Title:	Method of Predicting Outcome of a Stroke Using EEG
Applicant:	The University of Queensland
Our Ref:	030487PC/CA

We refer to the Written Opinion (mailed 8 July 2004) of the International Searching Authority in relation to the above application.

We **enclose** the applicant's comments in relation to the Written Opinion, to be included with the International Preliminary Examination Report on Patentability.

Yours respectfully
CULLEN & CO.

CLAUDE ANESE

Enc. As indicated above

PM

International Patent Application No. PCT/2004/000578 entitled "Method of Predicting Outcome of a Stroke Using EEG" in the name of The University of Queensland *et al*

APPLICANT'S COMMENTS

in relation to the

WRITTEN OPINION

The patent specification, as filed, contains 15 claims, all claims being method claims.

Claim 1 is directed to a method of predicting neurological developments resulting from a cerebral disorder in a patient, and includes the steps of acquiring EEG measures from the patient at at least two time-points, processing the acquired EEG measures to obtain a delta band power measure at each of the two time-points, and predicting clinical status of the patient from *the change in the delta band power measure between the two time-points.*

Claims 2-9 are appended to claim 1.

Claim 10 is directed to a particular embodiment of the method of claim 1, namely a method of predicting functional outcome of a stroke in a patient. This method also includes acquiring EEG data from the patient, determining the delta band frequency at which peak power occurs and the power measure associated with this peak frequency, *subtracting the power measure at one time-point from the corresponding power measure at a subsequent time-point*, and *predicting stroke outcome from a derivative value of the difference between the two power measures.*

Claim 11 is appended to claim 10.

Claim 12 is also directed to a particular embodiment of claim 1, namely a method of predicting neurological developments from a stroke or similar cerebral ischaema in a person. It includes the steps of acquiring EEG data from the person and processing the

EEG data to obtain a measure of power in the delta band at at least two time-points, and predicting neurological outcome *from the change in the power measure between the two time-points*.

Claims 13 to 15 depend from claim 12.

All claims involve obtaining measures of power in the delta band at at least two time-points, and predicting clinical status or outcome from the difference between the delta band power measures at the two time-points.

Applicant submits that the interpretation of references D1 to D4 in the Written Opinion is inaccurate. Applicant further submits that none of the references teaches or suggests deriving delta band power measures from EEG data at two different points in time, and utilising the change over time in the delta band power measures to predict functional (clinical or neurological) outcome.

Although D1 may suggest that regional distribution of slow wave activity differs between schizophrenics and depressives, there is no disclosure or suggestion of using the variation of delta band power *over time* to predict clinical outcome of a cerebral disorder. It would appear from the abstract that the method taught by this reference relies on spatial distribution of delta-rhythm power spectrum characteristics, and in particular differences between the left and right hemispheres of the brain, rather than temporal changes in delta band power measures.

D2 discloses method for predicting outcome of hypoxic ischemic disorders in newborns possessing respiratory distress syndrome. Again, it appears that, while EEG data may be acquired at subsequent intervals of time, the method is based on an analysis of spatial distribution at each time point, rather than temporal changes in the scalp delta power between time points.

D3 and D4 were published after the claimed priority date of the subject application. In any event, D3 teaches the estimation of the state of consciousness (i.e. awake or asleep) on the basis of intracranial EEG, and does not teach or suggest using changes in computed delta band power measures obtained from scalp EEG data over time to

predict functional outcome of a cerebral disorder. Similarly, D4 teaches a method for real-time monitoring (i.e. during surgery), and does not involve the use of changes in delta band power measures over time to predict functional outcome.

The remaining references are less relevant, and are acknowledged in the Written Opinion as not disclosing methods of predicting neurological developments from changes in delta band power measures over time.

In summary, applicant submits that none of the cited references discloses, or suggests, predicting neurological developments in a patient from the difference in delta band power measures at two time-points.